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No. 95-35

IN THE
Supreme Court of the United States

OCTOBER TERM, 1995

ORTHO PHARMACEUTICAL CORP.,
Petitioner,

v.

GENETICS INSTITUTE, INC. AND AMGEN INC.,
Respondents.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF ON BEHALF OF AMGEN INC. IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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STATEMENT PURSUANT TO SUPREME COURT RULE 29.1

Amgen Inc. has no parent companies and no subsidiaries (except wholly-owned subsidiaries).

TABLE OF CONTENTS

STATEMENT PURSUANT TO SUPREME COURT RULE 29.1 i

TABLE OF AUTHORITIES iii

STATEMENT OF THE CASE 1

A. The Patent In Suit and the Relevant License Provisions 2

B. The District Court Decision 5

C. The Court of Appeals' Affirmance 7

SUMMARY OF THE ARGUMENT 9

REASONS FOR DENYING THE PETITION 10

A. Ortho's "Questions Presented" Are Not Fairly Raised by the Facts of This Case 10

B. Ortho's Petition Fails to Justify This Court's Review 12

C. Even If Ortho Had Sufficient Rights Under the '008 Patent To Confer Standing, Ortho Contractually Bargained Away Any Such Right to Bring Suit 15

CONCLUSION 15

TABLE OF AUTHORITIES

CASES

A.L. Smith Iron Co. v. Dickson,
141 F.2d 3 (2d Cir. 1944) 14

Amgen Inc. v. U.S. Int'l Trade Comm'n,
902 F.2d 1532, 14 USPQ2d 1734 (Fed. Cir. 1990) . 3n, 12

Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd. and Genetics Institute, Inc.,
927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), *cert. denied*, ___ U.S. ___, 112 S.Ct. 169 (1991) 3, 5

Brunswick Corp. v. United States,
19 USPQ2d 1702 (Ct. Cl. 1991) 13n

Crown Die & Tool Co. v. Nye Tool & Machine Works,
261 U.S. 24 (1923) 9

Independent Wireless Telegraph Co. v. Radio Corp. of America,
269 U.S. 459 (1926) 2, 9, 10, 13

Panaview Door & Window Co. v. Van Ness et al.,
135 F. Supp. 253, 107 USPQ 31 (S.D. Cal. 1955) . . 15

Pratt & Whitney Co. v. United States,
153 F. Supp. 409, 114 USPQ 246 (Ct. Cl. 1957) . . . 13

Sanofi, S.A. v. Med-Tech Veterinarian Products, Inc.,
222 USPQ 143 (D. Kan. 1983) 13

Waterman v. McKenzie,
138 U.S. 252, 11 S.Ct. 334 (1891) 7, 10, 11

Western Elec. Co. v. Pacent Reproducer Corp.,
42 F.2d 116 (2d Cir.), *cert. denied*,
282 U.S. 873 (1930) 7, 13, 14

SUPREME COURT RULES

Supreme Court Rule 10 12

Supreme Court Rule 10.1 . . . . . 12, 14

Supreme Court Rule 10.1(c) 14

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RESPONDENT AMGEN'S BRIEF IN OPPOSITION

Respondent Amgen Inc. ("Amgen") hereby opposes the Petition for Writ of Certiorari filed by Ortho Pharmaceutical Corp. ("Ortho") in this case.

STATEMENT OF THE CASE

This case involves the straightforward interpretation and application of specific contract provisions to determine the Petitioner's rights under a series of interrelated license agreements. Although somewhat complex, the interpretation of the

agreements posed no novel or difficult issues for the district court or the court of appeals below, both of which reviewed the facts in detail and both of which arrived at the same legal conclusion.

Ortho's Petition for Writ of Certiorari improperly mischaracterizes the facts of the case and the holdings below in an unavailing attempt to invent an "important question" of law where no such question exists. Ortho's assertion that the court of appeals has somehow re-written the law of standing in patent cases by "effectively overruling" this Court's decision in *Independent Wireless Telegraph Co.* v. *Radio Corp. of America*, 269 U.S. 459 (1926) is wrong because all that the court of appeals in fact did was to hold that Ortho was a non-exclusive licensee under the license agreement and as such lacked standing to sue. The factual prerequisite upon which Ortho's petition is laid, namely that Ortho holds an exclusive field-of-use license under the patent in suit, is incorrectly presumed as a given by the Petition. Yet such a finding is the very issue decided against Ortho by both courts below. The district court and the court of appeals each properly concluded that the rights of Ortho under the license agreement simply fall far short of the requisite ownership interest in the patent required for standing to sue. Both lower courts reached their consistent conclusions by applying ordinary principles of contract law to the facts, in complete harmony with this Court's guiding precedents, including *Independent Wireless*.

A. *The Patent In Suit and the Relevant License Provisions*

The patent at issue in this case, United States Patent No. 4,703,008 ("the '008 patent") issued on October 27, 1987, and is solely owned by Amgen. This patent claims DNA sequences that encode human erythropoietin ("EPO"), as well as vectors and host cells transformed or transfected with such

DNA sequences. This same patent was held valid (in part) and infringed in the prior appeal from this action, *Amgen, Inc.* v. *Chugai Pharmaceutical Co., Ltd. and Genetics Institute, Inc.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), *cert. denied*, ___ U.S. ___, 112 S.Ct. 169 (1991). The '008 patent does *not* claim the EPO product or any process[1] for making such an EPO product. Rather, it covers the biologic materials that are used to produce recombinant EPO.

On September 30, 1985, before the '008 patent issued, Amgen and Ortho entered into a Technology License Agreement and a Product License Agreement (collectively, the "License Agreements") directed to three therapeutic products produced by recombinant DNA technology: EPO, human interleuken-2 (IL-2), and hepatitis B vaccine, as well as processes for their manufacture.[2] The two other recombinant products, IL-2 and hepatitis B vaccine, are neither covered by the '008 patent nor otherwise involved in this action.

The principal grant of rights in the License Agreements is found in Paragraph 2.01, which contains two subparagraphs, (a) and (b). Subparagraph (a) grants to Ortho:

> an exclusive license to make in one location, have made, and use LICENSED KNOW-HOW, LICENSED PATENTS and LICENSED PRODUCTS in the LICENSED TERRITORY in the LICENSED FIELD and to sell LICENSED PRODUCTS in the LICENSED TERRITORY.

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[1] In prior litigation involving the '008 patent, the Federal Circuit affirmed the decision that the '008 patent does not cover a process for producing EPO. *Amgen, Inc.* v. *U.S. Int'l Trade Comm'n*, 902 F.2d 1532, 14 USPQ2d 1734 (Fed. Cir. 1990).

[2] For purposes related to this petition, the License Agreements differ only as to the time period of their effect. The Technology License Agreement became effective on September 30, 1985, and remained in effect through about August, 1988, when the Product License Agreement superseded it. The pertinent terms of the agreements are identical.

In Subparagraph (b), Amgen grants to Ortho:

> an exclusive license, except as against Amgen's rights under this AGREEMENT in the LICENSED TERRITORY, to make EPO in one location in the United States for use and sale outside the LICENSED TERRITORY. . . .

The license granted under subparagraph 2.01(b) is not specifically directed or limited to *patent* rights.[3] Critically, Amgen's own right to make EPO in the licensed territory is expressly reserved.

In the License Agreements, Amgen and Ortho expressly allocated the right to bring suit against third parties for infringement of patent rights covered by the License Agreements. Amgen specifically retained "the right . . . to bring, defend and maintain any appropriate suit or action" for infringement. (A. 15).[4] Pursuant to Paragraph 8.02 of the License Agreements, only "[i]n the event Amgen fails to take action with respect to such matters within a reasonable period, not more than six (6) months, following receipt of such notice and evidence, Ortho shall have the right . . . to bring, defend and maintain any appropriate suit or action." Further, "[a]bsent an agreement between the parties to jointly bring any action or suit hereunder and share the expenses thereof, any amount recovered in any such action or suit shall be retained by the party bearing its expenses thereof." (A. 16.) The License Agreements do not grant Ortho any unconditional right to bring suit for infringement under the licensed '008 patent. Instead, Ortho's limited right to sue and collect damages from third

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[3] In contrast to Subparagraph 2.01(a), which specifically grants rights under "LICENSED PATENTS" and other intellectual property rights.

[4] All appendix designations herein refer to the printed decisions of the courts below, as annexed to Ortho's Petition.

parties is expressly contingent on Amgen electing *not* to bring suit within a reasonable period.

Here, Amgen *did* bring a patent infringement suit against Genetics Institute (hereinafter "GI"), promptly after the issuance of the '008 patent in 1987. Amgen neither requested nor received any assistance from its licensee, Ortho, in support of that infringement action. Amgen bore the entire expense of litigating the validity and infringement of the '008 patent, including a three month trial on the merits, a subsequent appeal to the Federal Circuit by both parties, and a response to a petition for writ of certiorari by GI. On March 5, 1991, after three and one half years of litigation, at great effort and expense borne solely by Amgen, the Federal Circuit affirmed the validity and GI's infringement of the '008 patent. *Amgen, Inc.* v. *Chugai Pharmaceutical Co., Ltd. and Genetics Institute, Inc.*, 927 F.2d 1200 (Fed. Cir. 1991). Certiorari was denied. 112 S.Ct. 169 (1991).

B. *The District Court Decision*

After Amgen prevailed in the liability phase of its infringement suit against GI, Ortho filed a separate patent infringement action against GI seeking damages for the same infringing acts. (B. 3). In an attempt to bootstrap a position with respect to standing, the licensee Ortho named Amgen, the patent owner, as a defendant in the new lawsuit, and then sought to realign Amgen as an involuntary plaintiff (B. 4). Amgen moved to dismiss Ortho's amended complaint for failure to state a claim, on the ground that Ortho lacked standing to bring its action. In granting the motion, the district court specifically found that the license grant under Paragraph 2.01(a) and (b) is non-exclusive with respect to the claimed subject matter of the '008 patent (B. 21), and that Ortho therefore has no standing to enforce the '008 patent.

Noting that it is well settled that a non-exclusive licensee has no standing to sue for infringement (B. 11), the district court properly held that one test for exclusivity is whether or not the licensor has promised explicitly or implicitly not to grant any additional licenses for the "patented invention" to third parties. (B. 12, 13). The district court also correctly observed at the outset that it is not dispositive that the License Agreements merely use the term "exclusive license." (*Id.*)

The district court concluded that Paragraph 2.01 reserved for Amgen the right to make EPO in the United States, and "does not contain any implied promise by Amgen not to further sub-license its right to manufacture EPO in the U.S. using the inventions claimed under the '008 patent." (B. 16, 17). Thus, the district court concluded that Ortho's license under the '008 patent is not exclusive as to this licensed patent right, and Ortho lacks standing, as a matter of law, to sue Genetics Institute for infringement of the '008 patent. (B. 18, 23).

In disposing of Ortho's argument that GI's infringement occurred within the limited area of Ortho's claimed exclusivity, the district court correctly noted that the '008 patent claims cover only the DNA sequences, vectors and transfected host cells used to manufacture EPO, and do not cover the EPO product itself. (*Id.*) Thus, the *patent* rights licensed to Ortho are the right to make and use the patented precursor materials, in the United States, to make unpatented EPO. Amgen expressly reserved these same rights to itself under the same patent. (B. 21). Ortho urged that the additional qualification of the granting language ("to make EPO *for sale abroad*") created an exclusive patent right distinct from Amgen's co-extensive right to make EPO in the United States using the inventions of the '008 patent.

The district court ruled that no such exclusive patent right exists. Contrary to Ortho's mischaracterization of that ruling, the district court did *not* find that Ortho was granted an exclusive

patent right of the expansive scope it asserted, or that the license is unenforceable as an unlawful extension of the '008 patent. Rather, the district court held simply that Ortho's territorial exclusivity arises solely from *contract* rights, and not from any license under the '008 patent. The district court correctly concluded that, since Ortho has no exclusive patent rights, it has no standing to sue Genetics Institute for infringement of the '008 patent. (B. 21).

C. *The Court of Appeals' Affirmance*

As previously noted, Paragraph 2.01(b) of the License Agreement permits Ortho to make EPO in the United States for sale abroad. On appeal to the Federal Circuit, Ortho abandoned its argument of standing based on Paragraph 2.01(a) (*see* A. 12) but renewed its claim that Paragraph 2.01(b) constitutes an exclusive grant under the '008 patent. The Federal Circuit rejected this contention and affirmed the district court's ruling that Ortho's license under the '008 patent is non-exclusive.

The Federal Circuit noted at the outset that, under well-settled law, standing to sue for patent infringement is reserved to the patent owner, except in extraordinary circumstances "as where the patentee is the infringer, and cannot sue himself." (A. 6, *quoting Waterman* v. *McKenzie*, 138 U.S. 252, 255, 11 S.Ct. 334, 335 (1891)). An exclusive licensee seeking enforcement of the patent can sue, if at all, only together with the patentee or in the name of the patentee. (A. 7). A holder of a non-exclusive patent license, however, suffers no legal injury from infringement and, thus, has no standing to bring suit or even to join in a suit with the patentee. (*Id.*, *citing Western Elec. Co.* v. *Pacent Reproducer Corp.*, 42 F.2d 116, 118 (2d Cir.), *cert. denied*, 282 U.S. 873 (1930). The test of patent license exclusivity, and therefore co-plaintiff standing,

is whether or not the licensee possesses "beneficial ownership of a right to prevent others from making, using or selling *the patented technology*." (A. 10, 11) (emphasis added).

The Federal Circuit thus began its analysis by examining what portion of the license "in fact concerns the '008 patent." (A. 13). The appellate court agreed with the district court's conclusion that the grant in Paragraph 2.01(b) ". . . to make EPO in the United States . . ." necessarily carried the implied right to use the inventions of the '008 patent to do so. (A. 14). Recognizing that this granting clause expressly reserved to Amgen a co-extensive right under the '008 patent to make EPO in the United States, the Federal Circuit rejected Ortho's attempt to differentiate its limited license rights in the patent from Amgen's retained ownership rights. The *additional* contractual right to sell EPO abroad, as claimed by Ortho (A. 14), was held not to create an exclusive field-of-use patent right sufficient to confer standing:

> Ortho commingles its consent from Kirin-Amgen to sell EPO abroad . . . with the rights it received from Amgen under the U.S. patent to use the '008 technology. U.S. patent '008 provides no rights respecting the product EPO *per se*. . . . With respect to Ortho's right to sell unpatented EPO abroad, the [district] court correctly held that Ortho's right was not a proprietary right arising from the '008 patent.

(A. 15). Thus, the Federal Circuit concluded that Ortho holds only a bare, non-exclusive license to the invention claimed in the '008 patent. (*Id.*)

The Federal Circuit also rejected Ortho's alternate suggestion that the right to sue clause of Paragraph 8.02 conferred standing upon Ortho despite Ortho's lack of any exclusive right in the '008 patent. The requirement that a licensee have

beneficial ownership of at least some part of the patentee's proprietary rights, the court stated, cannot be overcome by a contractual allocation. (A. 16, 17, *citing Crown Die & Tool Co.* v. *Nye Tool & Machine Works*, 261 U.S. 24, 44 (1923). Since Ortho has only a non-exclusive right in the '008 patent, the Federal Circuits concluded, "the right to sue clause has no effect in this case." (A. 16.)

Finally, the Federal Circuit noted that Ortho had not claimed to be a necessary or indispensable party to Amgen's action against GI, did not appeal the denials of intervention in Amgen's litigation, and did not appeal the order deconsolidating its suit from Amgen's suit (A. 18). The Federal Circuit concluded from these facts that Ortho had "effectively consented and concurred to suit" in the name of Amgen, the patentee, alone. *Id.* Ortho has not raised this alternate ground for the appellate court's decision as an issue for review by this Court.

SUMMARY OF THE ARGUMENT

Two lower courts have reviewed Ortho's rights under the License Agreements, and both courts have concluded that Ortho holds only a non-exclusive license under the '008 patent in suit. Accordingly, under well-settled law properly applied by the courts below, Ortho does not have standing to sue for infringement of that patent. The questions presented for review by Ortho are mere hypotheticals that have no relation to the facts of this case. Because Ortho's patent rights fall short of those required to confer standing, the decisions of the courts below raise no conflict with past decisions of this Court (including *Independent Wireless*) and other courts defining the circumstances under which an exclusive patent licensee may bring suit to enforce the licensed patent.

REASONS FOR DENYING THE PETITION

A. *Ortho's "Questions Presented" Are Not Fairly Raised by the Facts of This Case*

Ortho's fundamental mischaracterization of its non-exclusive rights under the '008 patent in suit creates the risk of a mistaken belief that the questions presented raise issues appropriate to be decided by this Court. Ortho *presumes* in its Petition that it is an exclusive licensee under the '008 patent, even though both lower courts held that it was only a non-exclusive licensee. Ortho's charge that the Federal Circuit overruled this Court's decision in *Independent Wireless* is founded on this factually incorrect premise. In truth, the Federal Circuit properly applied, and certainly did not overrule, *Independent Wireless* in holding that a non-exclusive licensee has no standing to sue for infringement of the patent.

Legal standing to sue for patent infringement derives from the claimed patent rights granted to the patent owner. *Waterman* v. *McKenzie*, 138 U.S. at 255. Both lower courts correctly reviewed the License Agreements to determine what rights Ortho received under the '008 patent. In this case, the '008 patent claims the DNA sequences, vectors and host cells used to make EPO, and the patent does not extend to the EPO itself produced by using those patented materials. Simply restating the Federal Circuit's decision, Ortho lacks standing to sue GI for patent infringement because Ortho holds no proprietary right to exclude others from practicing the "patented invention" claimed by the '008 patent. Standing to sue for patent infringement cannot be "conferred" by what an infringer does later with an unpatented product, or by any additional contractual rights which Ortho may have received from Amgen.

In the License Agreement which defines the scope of Ortho's rights under the '008 patent, Amgen clearly retained the right to practice the "patented invention" itself, the right to grant

additional sub-licenses to practice the "patented invention," and the right to exclude others from the practice of the "patented invention," if necessary, by suing infringers. The Federal Circuit clearly held:

> With respect to patent rights, Ortho had an implied license to use the '008 invention in one location in the United States. It is undisputed that the right was non-exclusive inasmuch as Amgen had the right to license others to do the same. (A. 12).

Such a reservation of rights precludes both exclusivity and standing to Ortho under the long established precedent of *Waterman* v. *McKenzie* and its progeny. The Federal Circuit correctly noted that Ortho had conceded this point.

Ortho's license under the '008 patent is not exclusive within a field-of-use. The "exclusive field-of-use" repeatedly claimed by Ortho applies to a territory outside the U.S. granted to Ortho for sale of the *unpatented EPO product*. Ortho's right to sell EPO outside the United States is a contract right and not a patent right licensed under the '008 patent. Thus, Genetics Institute's ultimate disposition in a foreign country of the unpatented EPO product resulting from the infringing use in the United States of the DNA sequences, vectors and host cells claimed in the '008 patent is irrelevant to Ortho's standing to sue under that patent.

The district court and the Federal Circuit both correctly interpreted the License Agreements as conveying a non-exclusive license under the '008 patent. Paragraph 2.01(a), which expressly grants rights to Ortho in "Licensed Patents", is subject to Amgen's own right to grant further sub-licenses of the right to make EPO in the United States using the patented DNA sequences, vectors and host cells of the '008 patent. Ortho conceded this point in the appellate court. (A. 14). Para-

graph 2.01(b), which does not expressly grant any license under any patent, but which the courts below reasonably interpreted to create an implied license to use the patented inventions of the '008 patent "to make EPO in the United States", is expressly subject to Amgen's right to do the same. Only by reaching *beyond* the scope of the '008 patent claims, by commingling the right to sell EPO abroad granted to Ortho separately, can Ortho define a right which it does not share with Amgen. That right, however, is only a *contract* right as against Amgen, is not founded on the '008 patent, and therefore cannot create legal standing to sue as an exclusive patent licensee. (A. 14, 15).

The Federal Circuit has now twice considered the scope of the '008 patent as it bears on legal standing to sue. In the prior appeal from Amgen's International Trade Commission action, the Federal Circuit ruled that the scope of the '008 patent claims may not be extended from the claimed DNA sequences, vectors and host cells to encompass the *process* by which those precursor materials are used to make recombinant EPO. *Amgen, Inc* v. *U.S. Int'l Trade Comm'n*, 902 F.2d 1532, 14 USPQ2d 1734 (Fed. Cir. 1990). In the decision below, the Federal Circuit correctly rejected Ortho's contention that the '008 patent claims could be stretched even farther to encompass not only the process of making EPO using the patented materials, but the resulting EPO *product* as well.

B. *Ortho's Petition Fails to Justify This Court's Review*

Ortho's petition fails to raise any of the special and important reasons of Supreme Court Rule 10 which justify this Court's review. Contrary to Ortho's misrepresentations, the decision below does not conflict with the decisions of other United States Courts of Appeals or of this Court. *See* Supreme Court Rule 10.1(a). When viewed without the distorting lens of

Ortho's false premise that it holds an exclusive right to a patented field-of-use, the decisions of both the district court and the court of appeals below are entirely consistent with all of the relevant past decisions of this court and inferior courts. The *Independent Wireless* decision trumpeted by Ortho was *not* violated by the courts below. Rather, *Independent Wireless* presented a different fact situation in which the licensee was found to have an exclusive field-of-use license in the patented invention. Based on the finding that the license was exclusive, this Court there held that the exclusive licensee could sue for infringement by joining the patentee. The clear point of factual departure in comparison with the present case is the absence of an exclusive license in the patented invention.

The cases following *Independent Wireless* cited by Ortho to support its standing argument also all involved exclusive rights in a field-of-use of a patented invention, and not of the unpatented product resulting from the licensed practice of the patent in suit. In each of *Western Electric Co., Inc.* v. *Pacent Reproducer Corp.*, 42 F.2d 116 (2d Cir. 1930); *Sanofi, S.A.* v. *Med-Tech Veterinarian Products, Inc.*, 222 USPQ 143 (D.Kan. 1983); and *Pratt & Whitney Co.* v. *United States*, 153 F.Supp. 409, 114 USPQ 246 (Ct. Cl. 1957), a field-of-use license was exclusive because it defined an exclusive use *of the patented invention*.[5] What the holdings of these cases reveal is *not* that the decision below is a departure from a "previously unbroken line of authority" as incorrectly alleged by Ortho (Ortho Petition at 21), but that without the fundamental premise of an exclusive license to practice at least some defined portion of the patented invention, *Independent Wireless* and its progeny are factually not on point.

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[5] The fourth case cited by Ortho, *Brunswick Corp.* v. *United States*, 19 USPQ2d 1702 (Ct. Cl. 1991), is not a field-of-use case at all. Rather, that case involved the grant of an exclusive right to *make* and *sell* the patented invention to one particular customer.

The Federal Circuit decision here is wholly consistent with the holdings in these cases that require an exclusive license, and in no way departs from the accepted and usual course of judicial proceedings so as to call for the exercise of this Court's supervisory power. *See* Supreme Court Rule 10.1(a). Moreover, the decision of the Federal Circuit below upholds the important policies underlying the law of standing in patent infringement cases set forth by Judge Learned Hand in *A.L. Smith Iron Co.* v. *Dickson*, 141 F.2d 3, 6 (2d Cir. 1944), including the paramount interest of the patent owner in selecting the forum for defense of his patent rights, and the protection of the accused infringer from multiple suits resulting from the same act of infringement.

While Ortho complains that it was injured by GI's infringement, economic injury to a licensee is not sufficient to overcome these important policy considerations and confer standing to sue. *Id.* When, as here, a licensee holds less than an exclusive right under the patent, the "[p]ractice of the invention by others may indeed cause him pecuniary loss, but it does him no legal injury." *Western Elec. Co.* v. *Pacent Reproducer Corp.*, 42 F.2d at 118.

Perhaps most importantly, this case presents no new and important question of federal law which should be settled by this Court. *See* Supreme Court Rule 10.1(c). Rather, this case involves the interpretation of clauses in license agreements negotiated between the patent owner and its licensee. Of necessity, this case is fact-specific, hinging not only on the particular language of the contract between the parties, but also on the scope of the '008 patent licensed. No important question of federal law arises from such facts.

C. *Even If Ortho Had Sufficient Rights Under the '008 Patent To Confer Standing, Ortho Contractually Bargained Away Any Such Right to Bring Suit*

Finally, even if Ortho were assumed to have sufficient rights under the '008 patent to confer standing to sue for patent infringement, Ortho bargained away that right to sue to its licensor, Amgen, under Paragraph 8.02 of the License Agreements.

The License Agreements provide Amgen with the right of first option to sue infringers of the '008 patent regardless of the nature of the infringing acts. Amgen exercised that right by suing Genetics Institute after the '008 patent issued. Although the lower courts did not reach this ground for dismissing Ortho's suit, none of the facts necessary to determine this legal question are in dispute, and the judgments below may be upheld on the basis of this provision of the License Agreements alone. *See, e.g., Panaview Door & Window Co.* v. *Van Ness et al.*, 135 F.Supp. 253, 107 USPQ 31 (S.D.Cal. 1955) (district court dismissed an *exclusive* licensee's infringement action for want of capacity to sue where the agreement reserved for the licensor the unconditional right to bring suit, with the licensee having the subordinate right to sue should the licensor decline to do so).

Amgen has the right in the first instance to sue infringers, and, having elected to do so, Amgen alone is entitled to the damages awarded for such infringement.

CONCLUSION

Ortho has shown no special and important reason for this Court to exercise its discretionary power of review here. The fundamental factual premise underlying the questions presented in the petition is unsupported by the facts of the case.

The district court and the court of appeals below reviewed the uncontested facts, applied them to the contract in question, and reached the same legal conclusion. Ortho holds no exclusive patent license under the '008 patent. Ortho's petition for a writ of certiorari should be denied.

Respectfully submitted,

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